OCT 1 3 2005

K052244

Section 2 - 510(k) Premarket Notification Summary (as required by 807.92 (j))

Submitter:	InnoVision Medical Technologies, LLC
Date Prepared:	August 5, 2005
Contact Person(s):	Patricia L. Andrews 410-694-9450 (v) 410-694-8092 (f)
Device Trade Name:	IISIS
Device Common Name:	Accessory to continuous ventilator (respirator)
Classification Name:	Class II, 868.5895, 73 MOD
Substantially Equivalent To:	Bernoulli Ventilator Management System (K011861) Cardiopulmonary Corp. 200 Cascade Boulevard Milford, CT 06460
Device Description:	IISIS software provides continuous display of ventilator data at a central station and remote workstations. IISIS utilizes wireless technology to interface with most critical care and home care ventilators that have RS-232, Ethernet, or nurse call. IISIS is accessed and displays ventilator data and waveforms through web-based technology. IISIS provides real-time alarm annunciation, displays and stores ventilator settings, parameters, and ventilator waveforms as a secondary tool to the primary ventilator alarm and data display.
Indications for Use:	Intended to be used on a central monitoring station on mechanically ventilated patients in a hospital or hospital type environment. It is used to provide a secondary display of the ventilator data to the central station and to provide remote monitoring and alarm surveillance. IISIS is intended to supplement and not replace any part of the current device monitoring procedures.
Technological Comparison to Predicate Device:	The proposed and the predicate devices are both software programs that are used to provide a secondary display of ventilator data to the central monitoring

	station and to provide remote monitoring and alarm surveillance. The proposed and predicate software can be operated from a personal computer. The IISIS software has substantially equivalent features and specifications.
Non-Clinical Performance Data:	Validation testing was provided that confirms that IISIS V 1.0 performs all input functions, output functions and all required actions according to the functional requirements specified in the Software Requirements Specification. To ensure performance to specifications, Federal Regulations and User Requirements: • Software Development Practices • The Validation and Verification Process have been followed. Procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validation, and maintenance.
Adverse Effects on Health:	The potential hazards are identified in the Hazard Analysis and are controlled by: • Designing controls directed at the cause and/or • Introducing protective measures and/or • Warning the Users.
Conclusions:	The IISIS V 1.0 does not result in any new potential safety risks and performs in accordance with its intended use as well as the Bernoulli Ventilator Management System device currently on the market. InnoVision Medical Technologies, LLC considers features of the IISIS V 1.0 to be substantially equivalent to the features of Bernoulli Ventilator Management System (K011861).

Table 2 – (Section 2) 510(k) Premarket Notification Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2005

Innovision Medical Technologies, LLC
Ms. Patricia L. Andrews
Corporate Operations Coordinator
1302 Concourse Drive
Suite 302
Linthicum, Maryland 21090

Re: K052244
Trade/Device Name: IISIS, VERSION 1.0
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: II
Product Code: MOD
Dated: October 3, 2005
Received: October 4, 2005

Dear Ms. Andrews:

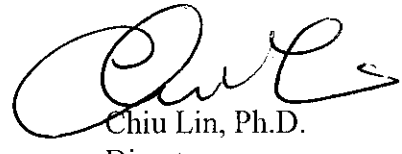
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: IISIS V. 1.0

INDICATIONS FOR USE:
Intended Use:

Indications For Use:

IISIS is intended to be used on a central monitoring station on mechanically ventilated patients in a hospital or hospital type environment. It is used to provide a secondary display of the ventilator data to the central station and to provide remote monitoring and alarm surveillance. IISIS is intended to supplement and not replace any part of the current device monitoring procedures.

Prescription Use __X__ OR Over-the Counter Use ____
Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052244